



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Wednesday, December 05, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.:
777-89/ Lysol Brand All Purpose Cleaner
DP Barcode: D344259

From: Ian Blackwell, Biologist
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Through: Karen Hicks, Team Leader
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To: Velma Noble, PM 31/ Drusilla Copeland
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):

N-Alkyl dimethyl benzyl ammonium chlorides

Other Ingredient(s):

Total:

% by wt.

1.1856

98.8144

100.0000

- 1) **BACKGROUND:** Reckitt-Benckiser, Inc., has submitted three acute toxicity studies "to support the change in tox category from a Category II (WARNING) to Category III (CAUTION)." The three studies are:

- a) MRID Number 472125-01: Acute inhalation toxicity. Lab Study Number 9688-06.
- b) MRID Number 472125-02: Primary eye irritation. Lab Study Number 9689-06.
- c) MRID Number 472125-03: Primary skin irritation. Lab Study Number 9690-06.

The Chemistry and Toxicology Team (CTT) notes a few things concerning this submission:

- 1. These three studies were conducted with All Purpose Cleaner, Formula #826-068. It is apparent from other CSFs that this differs from some past formulations of 777-89.
- 2. CTT is not able to find a review of 777-89 where a toxicity category II was assigned to a study.

2) **RECOMMENDATIONS:**

- a) CTT has not been able to locate any reviews where this product has been assigned toxicity category II. Thus, the classification of these studies might not lead to a change in precautionary labeling. For example, the registrant might have tested a formulation of Registration Number 777-89 that was assigned toxicity category I or II. If this is the case, this test of formulation #826-068 would not supersede the tests for the other formulation. So, the precautionary labeling of this product
- b) The acute inhalation toxicity study is acceptable. However, there is one caveat. As noted previously, this test material was one of several formulations of Registration Number 777-89. The stipulation is that the results of this study only apply to Formula #826-068.
- c) The primary eye and skin irritation studies are acceptable. As with the acute inhalation toxicity study, the classification of these studies specifically applies to Formula #826-068.
- d) The toxicity categories of the acute oral and acute dermal toxicity studies listed below in the acute toxicity profile come from the 1/19/2001 review of 777-IO(-89). It is possible that there are later acute toxicity reviews of 777-89 that may supersede this 1/19/2001 review. If so, these three toxicity categories may need to be revised.

The acute toxicity profile for Registration Number 777-89, Formulation #826-068 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	Not known	IV	Acceptable
Acute Dermal Toxicity	Not known	IV	Acceptable
Acute Inhalation Toxicity	472125-01	IV	Acceptable
Primary Eye Irritation	472125-02	IV	Acceptable
Primary Skin Irritation	472125-03	IV	Acceptable
Dermal Sensitization	Not known	Nonsensitizer	Acceptable

3) **LABELING:**

- a) Based upon the results of these studies, no precautionary labeling is required for Registration Number 777-89, Formulation #826-068.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 31
MRID No.: 472125-01

Reviewer: I. Blackwell
Study Completion Date: 3/27/2006
Lab Study No.: 9688-06

Testing Laboratory: Stillmeadow, Inc.
Author: Lori Carter, B.A.

Quality Assurance (40 CFR §160.12): Included

Test Material: All Purpose Cleaner Dilutable, Formula 826-068, GLP Batch 1151-154
Concentration: (Determined analytically) 2.20 mg/L

Species: Sprague-Dawley rat
Weight: Males=303-310 g Females=192-212 g
Age: 9 weeks
Source: Texas Animal Specialties

Summary:

1. **LC₅₀ (mg/L):**
Males > 2.20 mg/L
Females > 2.20 mg/L
Combined > 2.20 mg/L
2. **The estimated LC₅₀ is greater than 2.20 mg/L**
3. **MMAD:** 2.7 μm
4. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.20 mg/L	0/5	0/5	0/10

Chamber Atmosphere

Dose Level	MMAD	GSD	particles < 4.4 μm
2.20 mg/L	2.7 μm	6.3 μm	66.295

Chamber Environment	
Chamber Volume	500 liters
Airflow	22.1 LPM
Temperature	22.6-24.4° C
Relative Humidity	63.3-67.6%

Clinical Observations: Piloerection.

Gross Necropsy Findings: No observable abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31 **Reviewer:** I. Blackwell
MRID No.: 472125-02 **Study Completion Date:** 4/13/06
Lab Study No.: 9689-06

Testing Laboratory: Stillmeadow, Inc.
Author(s): Janice O. Kuhn, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: All Purpose Cleaner Dilutable, Formula 826-068, GLP Batch 1151-154
Dosage: 0.1 mL

Species: New Zealand White albino rabbit **Sex:** 2 males + 1 female
Weight: Males= 2.8-3.0 kg **Age:** Approx. 16 weeks
Female= 3.2 kg
Source: Nichols Rabbitry, Inc.

Summary:

- Toxicity Category:** IV
- Classification:** Acceptable

Procedure (Deviations From §81-4): None observed.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	3/3	0/3	0/3	0/3	---	---	---	---

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31
MRID No.: 472125-03

Reviewer: I. Blackwell
Study Completion Date: 3/14/06
Lab Study No.: 9690-06

Testing Laboratory: Stillmeadow, Inc.
Study Director: Janice O. Kuhn, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: All Purpose Cleaner Dilutable, Formula 826-068, GLP Batch 1151-154
Dosage: 0.5 mL

Species: New Zealand albino	
Weight: Males= 2.8-3.7 kg	Age: Approx. 13 weeks
Female=2.550	
Source: Nichols Rabbitry, Inc.	Sex: 2 males + 1 female

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations From §81-5): None

Results: Very slight erythema was observed in 2/3 test material-treated animals 1 hour after treatment. Twenty-four hours and forty-eight hours after treatment, 1/3 animals displayed very slight erythema. No other irritation was observed during the study.